IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kawamura et al.
Serial No. :	10/585,168
For:	TULOBUTEROL ADHESIVE PATCH
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DECLARATION UNDER 37 C.F.R. 1.132

Dear Sir:

1. I, Naohisa KAWAMURA, hereby declare and state the following:

2. I am a citizen of Japan. I reside at Saitama, Japan.

3. I have a degree in pharmaceutical sciences from the Nihon University. I have been continuously employed by NIPRO PATCH CO., LTD. since 1991, working in the field of research and development of new medical products. My current position is a Group Manager of New Product Research Group.

4. I am a co-inventor of the subject matter of the above-identified patent application.

5. As a person having ordinary skill in the art of tulobuterol patches, I have reviewed United States Patent Nos. 5,254,348, to Hoffman et al., 5,185,212, to Spada et al., and 6,632,906, to Kamiyama et al., as well as International Application Publication No. WO 86/06281, to Wick. I have also reviewed the Final Office Action mailed on September 9, 2010, and the Advisory Action mailed on November 18, 2010 in the present application. It is my opinion that Hoffman, Spada, Wick, and Kamiyama do not disclose or suggest, either alone or in combination, each and every feature of the claims of the present application. The teachings of each, particularly those of Hoffman and Spada, cannot be combined, for the technical reasons discussed below.

6. Hoffman is directed to a transdermal therapeutic system with tulobuterol as an active substance (Abstract). The active substance is in a matrix containing at least one polystyrene-1,3-diene-polystyrene (SDS) block copolymer (col. 2, l. 53-58).

7. In the present application, a commercially available tulobuterol patch named "H Tape" was compared with the patches of the present claims. The H Tape patch was named "Comparative Example 3" (CE3) (¶41, present specification). As shown in the experimental data provided in the present specification, the patch of CE3 performed much worse than the patch of the present claims in critical areas such as skin permeability (¶50), skin irritation (¶54), adhesive force (¶62), and autohesion (¶62). Autohesion is a measure of how the patch adheres to itself, where a high value of autohesion is considered undesirable (¶59).

8. The H Tape patch used for CE3 was made by Nitto Denko, and to my knowledge was the only tulobuterol patch available in Japan at the time the data in the present application was collected. The H Tape patch is discussed in ¶2 of the

background section of the present specification, and shown and described in full detail in International Application Publication No. WO 97/14411. This application also issued as Australian Patent No. 707661, and is attached in Exhibit 1 of this declaration.

9. The patches of Hoffman are substantially the same as the H Tape patch of CE3, and it is my opinion that the Hoffman patch would exhibit similar properties and performance criteria as the patch of CE3, since they both use equivalent synthetic rubbers. The H Tape patch of CE3 contained a synthetic rubber, polyisobutylene. On p. 3, l. 13-16 of AU 707661, the inventors stated that the synthetic rubber may be "polyisobutylene, polyisoprene, styrene-butadiene block copolymer, styrene-butadiene-styrene block copolymer (SBS), styrene-isoprene-styrene block polymer (SIS) and mixtures thereof." (emphasis added) The styrene-butadiene block copolymer listed in AU 707661 is substantially the same as the SDS polymer in Hoffman. The above disclosure in AU 707661 establishes that, for purposes of use in tulobuterol patches, polyisobutylene (used in CE3) and styrene-butadiene block copolymer (the SDS of Hoffman) are substantially equivalent. Thus, one of ordinary skill in the art would expect that the SDS of Hoffman, like the polyisobutylene of CE3, would exhibit undesirable properties in adhesive patches.

10. In addition, Hoffman states several times throughout the reference that the entire invention is based on the combination of tulobuterol and SDS (Abstract, col. 2, l. 53-58, col. 3, l. 25-29). This is because the SDS polymer provides "structural-mechanical stability" (col. 3, l. 25-26), and improved release rate of the tulobuterol (col. 8, 7-9). In fact, the SDS was shown in the Examples of Hoffman to have a particularly effective reaction with tulobuterol, as comparative tests with salbutamol were not as favorable (col. 8, l. 9-14). As such, the SDS of Hoffman is a critical component, and one of ordinary skill in the art would never remove the SDS of Hoffman and substitute the 2-acetoacetoxyetyl methacrylate (AAEM) of Spada, as suggested in the Final Office Action, since Hoffman clearly states that SDS is particularly useful with tulobuterol.

11. Furthermore, Spada shows articles containing pressure-sensitive adhesives

with AAEM in an amount of 2% (e.g., Example 2). This is much, much less than the amount of AAEM that is required in the present claims, which is 10-45 wt% of the total weight of the acrylic pressure-sensitive adhesive agent. In the present claims, when the amount of AAEM is smaller than 10%, the oily substance-holding power and the cohesive strength will be reduced, and when it is larger than 45%, the network structure will become too dense, reducing the holding power for the plasticizer and other components.

I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and beliefs are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Dated: December 28, 2010

By: Nathan Hammond